

Gifts To Physicians Guidelines

Patients' should be confident that they are receiving their physicians' best care, uninfluenced by the interest of third parties. They trust that personal or financial benefits will not influence the medical decisions regarding the care they receive. Traditionally many gifts given to physicians by industry serve an important and socially beneficial function. For example, industry has long provided funds for educational seminars and conferences. In the last several years, however, many troubling practices are occurring. Industry money and influence has permeated virtually all levels of physician CME in the form of complimentary meals and entertainment, consultation fees, "shop and dash" functions, and pseudo-CME courses. These "gifts" give rise to some notion of reciprocity, which would likely undermine trust and weaken the patient-physician relationship.

Congress developed an interest in these activities and began to investigate them in the early 1990s. The Justice Department, along with other investigative agencies, has again recently expressed concern about the relationship between industry representatives and physicians. In the hope of averting government intervention, the American Medical Association developed guidelines that address these practices, which were also adopted by the Pharmaceutical Research and Manufacturers of America. These guidelines are part of the Ethical Opinions of the AMA. The Kentucky Medical Practice Act KRS 311.597 (4) requires that physicians "...conform to the principles of medical ethics of the American Medical Association...". The guidelines are based on the following principles:

- **Gifts should be a benefit to patients**
- **Gifts should be of educational value**
- **Gifts should be related to the physician's work**
- **Gifts need to be of modest value and not cash payments or equivalent payment**
- **There should be no strings attached. (Physicians should not require a thing of value from the representative.)**
- **The educational value of the activity must be the primary consideration in the physician's decision to attend.**

It would be unrealistic to propose that all meals, entertainment, or CME funding provided by pharmaceutical companies are unethical. The practice should be judged by degree. The concern is the pursuit of these practices to excess. **When the influence created by the meal, the entertainment, or any other activity, in and of itself, has the potential to alter the physician's prescribing patterns rather than the efficacy of the particular product being touted, it should be considered inappropriate.** It may also be considered illegal since federal law prohibits a physician from giving or receiving "anything of value" in exchange for a "referral".

To avoid the acceptance of inappropriate gifts, physicians should observe the following Opinion of the Council on Ethical and Judicial Affairs (E-8.061 Gifts to Physicians from Industry).

- (1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted.

The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members.

- (2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads).
- (3) The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where
 - (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and
 - (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.An appropriate disclosure of financial support or conflict of interest should be made.
- (4) Subsidies to underwrite the cost of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.
- (5) Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time.

Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting.

It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses.

It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

- (6) Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policymaking meetings of national, regional or specialty medical associations.

- (7) No gifts should be accepted if there are strings attached.

For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices.

In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

An addendum of questions and answers that adds clarity to these guidelines can be found at www.ama-assn.org.

Physicians do not belong to a trade but a profession and as such have an obligation to uphold this standard of ethics and to ensure they are properly enforced. The Kentucky Board of Medical Licensure will use these principles as a basis for deliberating on any complaint received regarding physician activities in this area.

Adopted: March 22, 2001

Addendum to Gifts to Physicians

Gift giving from the pharmaceutical, device and medical equipment industries to physicians has been a custom, and has often served a beneficial function for physicians and patients alike. But when gift giving is not practiced within the established ethical boundaries, the perception of conflict-of-interest is raised. Physicians, physicians in training and industry representatives should adhere to the *AMA Code of Medical Ethics, Opinion 8:061, "Gifts to Physicians from Industry"*, which offers seven basic guidelines on gifts.

The guidelines are not black or white but should be judged by degree so as to avoid the pursuit of these practices to excess. We offer the following clarification regarding subsidies for consultants.

The Opinion reads, **"It is appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expense."**

We would recommend these defining questions regarding Consultancies, Advisory Boards, Speakers Bureaus, etc.:

- Who is providing input and who is receiving it?
- Will input actually impact the company's decision-making?
- Is feedback provided to the physician that indicates true consulting activity?
- Is the company providing training intended to influence the content of the presentation?
- Will the invited physician truly be bringing expertise to the activities?
- Is the amount of genuine work greater than the amount of promotional or social time?
- Is there a notion of reciprocity?

We ask physicians to use good judgment so that patients can be confident that they are receiving their physicians' best care, uninfluenced by the interest of third parties. The Kentucky Board of Medical Licensure hopes this discussion helps all Kentucky physicians avoid inappropriate gifts.

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